

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
22 August 2002 (22.08.2002)

PCT

(10) International Publication Number  
**WO 02/064109 A3**

(51) International Patent Classification<sup>7</sup>: **A61K 9/127**,  
9/00, 35/78

CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,  
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,  
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,  
MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG,  
SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ,  
VN, YU, ZA, ZW.

(21) International Application Number: PCT/GB02/00620

(84) Designated States (*regional*): ARIPO patent (GH, GM,  
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),  
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),  
European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR,  
GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent  
(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR,  
NE, SN, TD, TG).

(22) International Filing Date: 14 February 2002 (14.02.2002)

**Declarations under Rule 4.17:**

(25) Filing Language: English  
(26) Publication Language: English  
(30) Priority Data:  
0103638.3 14 February 2001 (14.02.2001) GB  
60/280,044 30 March 2001 (30.03.2001) US  
09/827,158 5 April 2001 (05.04.2001) US  
0111597.1 11 May 2001 (11.05.2001) GB  
0121715.7 7 September 2001 (07.09.2001) GB  
09/951,022 12 September 2001 (12.09.2001) US

— as to the identity of the inventor (Rule 4.17(i)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)  
— of inventorship (Rule 4.17(iv)) for US only

(71) Applicant (for all designated States except US): **GW PHARMA LIMITED** [GB/GB]; Porton Down Science Park, Salisbury, Wiltshire SP4 0JR (GB).

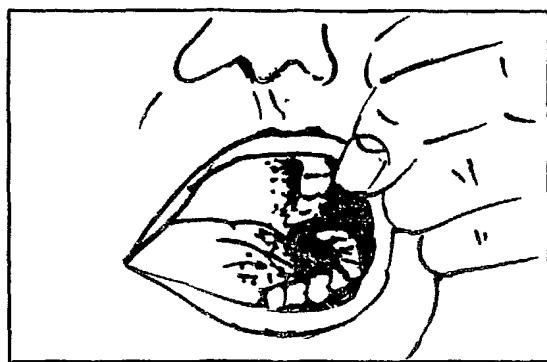
**Published:**

(72) Inventors; and  
(75) Inventors/Applicants (for US only): **WHITTLE, BRIAN** [GB/GB]; Wortley House, 16 Eastbourne Road, Hornsea, Yorkshire HU18 1QS (GB). **GUY, GEOFFREY** [GB/GB]; South House, Piddletrenthide, Dorchester, Dorset DT2 7QP (GB).  
(74) Agents: **BOULT WADE TENNANT** et al.; Verulam Gardens, 70 Gray's Inn Road, London WC1X 8BT (GB).  
(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,

— with international search report

[Continued on next page]

(54) Title: MUCOADHESIVE PHARMACEUTICAL FORMULATIONS



(57) Abstract: The invention relates to pharmaceutical formulations for use in the administration of lipophilic medicaments via mucosal surfaces. In particular the invention provides pharmaceutical formulations for use in administration of a lipophilic medicament via a mucosal surface which upon hydration form an emulsion containing the lipophilic medicament which is capable of adhering to a mucosal surface and allowing controlled release of the medicament. The invention further provides pharmaceutical formulations which contain, as active ingredients, specific combinations of cannabinoids in pre-defined ratios.

WO 02/064109 A3



**(88) Date of publication of the international search report:**

20 February 2003

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 02/00620

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC 7 A61K9/127 A61K9/00 A61K35/78

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, PAJ, EPO-Internal, CHEM ABS Data, BIOSIS, MEDLINE, PASCAL, EMBASE

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 560 625 A (CHRISTOPHER HOLLET COSTELLO; ET AL.) 2 February 1971 (1971-02-02) claims 1,3 column 1, line 28 - line 50 examples I,II,VII; table I examples II,VII; table VIII ---	1-5,8,9, 11,13,23
X	WO 95 25504 A (PHARMAVENE) 28 September 1995 (1995-09-28)  claims 1,4,5,15,20 page 13, paragraph 4 - page 14, paragraph 1 ---	1,2,9, 23-25, 27,28  -/-

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

## ° Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

21 October 2002

Date of mailing of the international search report

12.11.2002

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Rempp, G

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 02/00620

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 01 66089 A (GW PHARMA) 13 September 2001 (2001-09-13)  claims 1,8-11,13,14,18,23,24,26 page 3, line 30 - line 31 ---	1,2, 14-17, 23-27, 33-37, 40-45, 99,113, 114
X	EITAN ALHANATY; ET AL.: "Osmotic fragility of liposomes as affected by antihemolytic compounds" BIOCHIMICA ET BIOPHYSICA ACTA, vol. 339, no. 1, 1974, pages 146-155, XP008008726 the whole document ---	109
A	WO 00 25127 A (UNIV MISSISSIPPI) 4 May 2000 (2000-05-04) ---	
A	PATRICIA S. FETTERMAN ET AL.: "CONSTITUENTS OF CANNABIS SATIVA L. I: PROPYL HOMOLOGS OF CANNABINOID FROM AN INDIAN VARIANT" JOURNAL OF PHARMACEUTICAL SCIENCES., vol. 61, no. 9, September 1972 (1972-09), pages 1476-1477, XP002217537 AMERICAN PHARMACEUTICAL ASSOCIATION. WASHINGTON., US ISSN: 0022-3549 -----	

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/GB 02/00620

### Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
  
2.  Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
  
3.  Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
  
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
  
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
  
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

#### Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-45,47-63,112, (partially) 99-103,  
(partially) 113-114

Pharmaceutical formulation for delivery of a lipophilic medicament through a mucosal surface comprising at least a lipophilic medicament and at least one self emulsifying agent, wherein upon hydration forms an emulsion which is capable of adhering to a mucosal surface.

2. Claims: 64-90,97,98,104-107, (partially) 99-103,113,114

Pharmaceutical formulation comprising cannabidiol and tetrahydrocannabinol, or tetrahydrocannabivarin and cannabidivarin in a predefined ratio by weight.

3. Claims: 91-96, 108, (partially) 99, (partially) 113-114

Pharmaceutical formulation comprising THC and THCV wherein the amount by weight of THCV is approximately equal or greater than the amount by weight of THC.

4. Claims: 109-111

Use of cannabidiol to extend the shelf life of a pharmaceutical product which comprises one or more other biologically active components.

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International Application No

PCT/GB 02/00620

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US 3560625	A 02-02-1971	AT 277448 B BE 711048 A DE 1667872 A1 ES 349148 A1 FR 7355 M GB 1209849 A IE 32432 B1 NL 6802422 A		29-12-1969 01-07-1968 15-07-1971 01-09-1969 20-10-1969 21-10-1970 08-08-1973 21-08-1968
WO 9525504	A 28-09-1995	AU 696855 B2 AU 2102495 A CA 2185803 A1 EP 0788346 A1 JP 9510712 T WO 9525504 A1 US 5952004 A US 5897876 A		17-09-1998 09-10-1995 28-09-1995 13-08-1997 28-10-1997 28-09-1995 14-09-1999 27-04-1999
WO 0166089	A 13-09-2001	GB 2361869 A AU 3760801 A WO 0166089 A2 AU 7430701 A WO 0197780 A2		07-11-2001 17-09-2001 13-09-2001 02-01-2002 27-12-2001
WO 0025127	A 04-05-2000	US 6365416 B1 AU 1234800 A EP 1133688 A1 JP 2002528718 T US 2002086438 A1 WO 0025127 A1 US 2002039795 A1		02-04-2002 15-05-2000 19-09-2001 03-09-2002 04-07-2002 04-05-2000 04-04-2002